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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,783	08/07/2001	Jacky G. Duchamp	ACSC-60113	5784

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/924,783

**Applicant(s)**

DUCHAMP, JACKY G.

**Examiner**

Ann Y. Lam

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,6-9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-9 and 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 6-9 and 11-14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 11-12 and claim 13, lines 11-12, both claim "a distal end the inner tubular member extends through the balloon interior". This language is grammatically incorrect. It appears that Applicant intended to have the word —of—after "distal end". (However, even this language is indefinite because in Applicant's invention (see figure 2), the distal *end* of the inner tubular member does not extend through the balloon interior, rather it is the distal *portion* of the inner tubular member that extends through the balloon interior.)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bazell et al., 3,884,242, in view of Inoue, 5,100,386.

Bazell discloses the invention substantially as claimed.

More specifically, Bazell et al. discloses a catheter shaft (2) having an inflation lumen (9), a guidewire receiving lumen (29) extending to a port (near 25) at the catheter shaft distal end and an inflation lumen (9), the guidewire receiving lumen (29) being in communication with a port (near 25); a balloon (16) having a proximal balloon shaft section adjacent the balloon proximal end, and a distal balloon shaft section adjacent the balloon distal end and being adhesively secured to the catheter, see column 7, lines 42-50, and column 10, lines 41-44; the balloon distal shaft section (45) having an outer surface tapering distally; and a tip member (19) having a proximal-most end (22) and a distal-most end (25), an outer surface tapering distally to a smaller outer diameter from the proximal-most end of the distal tip member toward the distal-most end of the distal tip member, see column 8, lines 6-12, and lines 47-49, a lumen in fluid communication with the catheter shaft guidewire receiving lumen (see Figure 3), and a proximal portion adhesively secured to the balloon distal shaft section, see column 8, lines 50-61, and the catheter shaft, see column 7, lines 64-67.

Although Bazell discloses a guidewire receiving lumen (29) and an inflation lumen (9), Bazell does not disclose an inner tubular member disposed within at least a portion of the outer tubular member inflation lumen and defining at least in part a

guidewire receiving lumen, the guidewire receiving lumen being in communication with a port at the catheter distal end.

Inoue also discloses a balloon catheter having an inflation lumen and a guidewire lumen. Inoue discloses an inner tubular member (14) disposed within at least a portion of the outer tubular member inflation lumen (18) and defining at least in part a guidewire receiving lumen (see column 4, lines 22-24, and figure 1), the guidewire receiving lumen being in communication with a port at the catheter distal end (see figure 1).

Since Bazell teaches that the invention is directed towards an improved cuff and catheter tip assemblies for catheter tubes of all types (see abstract), wherein the tapered profile of the tip assembly reduces tissue lesions upon insertion or removal (see column 1, lines 20-26), it would have been obvious to modify the Inoue catheter to include the cuff and tip assembly of the Bazell catheter in order to provide an improved cuff and catheter tip which reduces tissue lesions, as taught by Bazell.

As to the following claims, Bazell discloses the following. As to claim 2, the catheter shaft (2) extends distally beyond the balloon distal end, see Figure 7.

As to claim 3, the tip member proximal end forms a butt-joint with the balloon distal shaft section, see column 10, lines 35-37, and see column 12, lines 39-40.

As to claim 4, the tip member proximal ends (36) extends proximally over the distal end of the catheter shaft, see Figure 7.

As to claim 11, the adhesive for forming the adhesive seal between the balloon distal shaft section and the catheter shaft extends along the length of the balloon distal

shaft section, see column 7, lines 42-50, and see reference number 17 and 17', in Figures 3 and 7.

As to claim 12, the adhesive is capable of being cured, see column 7, lines 64-67.

As to claims 13 and 14, Bazell et al. discloses the step of curing the adhesive to form the catheter assembly in column 7, lines 42-47. Also, the tip member is bonded to the balloon distal shaft section, see column 8, lines 46-57, and see also column 7, lines 42-51 and column 5, lines 37-38.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bazell et al., 3,884,242.

Bazell et al. discloses the invention substantially as claimed. However, Bazell et al. does not disclose the length that the distal end of the catheter shaft extends distally beyond the balloon distal end, nor the length that the proximal end of the tip member extends distally over the catheter shaft as claimed by Applicant. However, Bazell et al. teaches that various modifications within the scope of the invention can be made by one of ordinary skill in the art without departing from the spirit thereof, see column 14, lines

5-8. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the Bazell et al. device with the various lengths as claimed by Applicant, as modifications that are within the scope of the invention as taught by Bazell et al.

***Allowable Subject Matter***

Claim 15 is allowed.

***Response to Arguments***

With respect to Applicant's arguments, although allowable subject matter was indicated in the last Office action, Examiner believes that the above rejections are proper upon further consideration of the claims. Examiner apologizes for any inconvenience.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

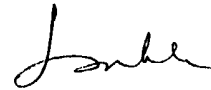
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



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03/24/04